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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/462,472

01/14/2000

HIROSHI MATSUI

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10/04/2006

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EXAMINER

FRONDA, CHRISTIAN L

ART UNIT

PAPER NUMBER

1652

DATE MAILED: 10/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/462,472

Applicant(s)

MATSUI ET AL.

Examiner

Christian L. Fronda

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 April 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18, 20-22, 25, 27 and 28 is/are pending in the application.
- 4a) Of the above claim(s) 1-12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13-18, 20-22, 25 and 27 is/are rejected.
- 7) ☒ Claim(s) 13-18, 20-22, 25, 27 and 28 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 January 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>04/20/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. Claims 1-18, 20-22, 25, 27, and 28 are pending in the instant application. Claims 1-12 have been previously withdrawn from consideration.
2. Claims 13-18, 20-22, 25, 27, and 28 under consideration in this Office Action. New rejections are presented in the instant Office Action.
3. The previous objection to claim 13 has been withdrawn in view of applicants' amendment to claim 13, where the correct spelling of "phosphoglucose isomerase" is recited.
4. The rejection of claim 16 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement has been withdrawn in view of applicants' amendment to the claim filed on 04/20/2006.
5. The rejection of claims 13 and 27 under 35 U.S.C. 103(a) as being unpatentable over Mascarenhas et al. in view of Gelpi has been withdrawn in view of applicants' amendment to the claims filed on 04/20/2006.
6. The rejection of claims 14, 15, 17-21 under 35 U.S.C. 103(a) as being unpatentable over Mascarenhas et al. in view of Gelpi as applied to claims 13 and 27, and further in view of Neuhard et al has been withdrawn in view of applicants' amendment to claim 13 filed on 04/20/2006.
7. The rejection of claim 22 under 35 U.S.C. 103(a) as being unpatentable over Mascarenhas et al. in view of Gelpi and Neuhard et al., as applied to claims 14, 15, 17-21, and further in view of Rolfes et al. has been withdrawn in view of applicants' amendment to claim 13 filed on 04/20/2006.
8. The rejection of claim 25 under 35 U.S.C. 103(a) as being unpatentable over Mascarenhas et al. in view of Gelpi as applied to claims 13 and 27, and further in view of Accession P09452 has been withdrawn in view of applicants' amendment to claim 13 filed on 04/20/2006.

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Claim Objections

9. Claims 13-18, 20-22, 25, and 27 are objected to because of they recite non-elected subject matter.

Applicants' arguments filed 04/20/2006 have been fully considered but they are not persuasive in view of the petition decision dated 06/12/2006. Of particular relevance is page 6 of the petition decision dated 06/12/2006, which is reproduced below:

“Applicants' arguments are not persuasive as the examination standard provided by MPEP 803.02 does not apply to PCT. According to Administration Instructions, Annex-, Part B, the species election between the enzymes can be maintained even though they all belong to a recognized class of chemical compounds because all the enzymes do not share a common structure and at least one Markush alternative is not novel over the prior art. Specifically, Seeger et al. (copy enclosed) teach the enzyme xanthosine phosphorylase as claimed and Mori et al. (copy enclosed) teach the enzyme inosine-guanosine kinase as claimed.”

In view of the petition decision dated 06/12/2006, applicants are required to cancel or amend the claims to recite the elected subject matter of phosphoglucose isomerase.

Claim Rejections - 35 U.S.C. § 112, 2nd Paragraph

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claim 16 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 16, the phrases “lysine residue corresponding to position 326 of the *Escherichia purF* gene product” and “proline residue corresponding to position 410 of the *Escherichia purF* gene product” render the claim vague and indefinite since the specific SEQ ID NO of the *purF* gene product has not been recited and by reciting the word “corresponding”, which is unclear as to whether the claim is actually referring to the specific positions of 326 and 410.

Amending the claim to recite that the lysine residue at position 326 and the proline residue at position 410 of a specific SEQ ID NO may overcome the rejection.

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Claim Rejections - 35 U.S.C. § 112, 1st Paragraph

12. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

13. Claims 13-18, 20-22, 25, and 27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants' arguments filed 04/20/2006 that the rejection of the claims as failing to comply with the written description requirement is not appropriate for the reason promulgated by the *Capon* Court (*Capon v. Eshhar*, 418 F.3d 1349, 76 USPQ2d 1078 (Fed. Cir. 2005)) has been considered but is not persuasive. The examiner respectfully disagrees with the arguments for reasons of record as further explained below.

The instant invention, unlike *Capon*, is directed toward methods using genetically altered microorganisms belonging to the genus *Escherichia* to produce any purine nucleoside, where the altered microorganisms are modified to block a reaction catalyzed by phosphoglucose isomerase. The specific mutations to the gene encoding phosphoglucose isomerase resulting in any microorganism having the ability to overproduce any purine nucleoside compared to an untransformed microorganism have not been described by the specification as being well-known in the art. This contrasts with *Capon* which involves chimeric genes used in gene therapy. Thus, the conclusions reached from *Capon* are not applicable to the instant invention.

Example 8 of the specification shows that primers of SEQ ID NO: 22 and SEQ ID NO: 23 were used to amplify the E.coli *pgi* gene which encodes phosphoglucose isomerase, the *pgi* gene was mutated by removing a fragment of 500bp, and the mutated *pgi* gene transformed into E.coli host cells by homologous recombination, where transformed E.coli host cells FADRaddpgi and FADRaddedpgi produced increase amounts of inosine compared to untransformed E. coli host cells (see Table 10).

Amending the claims to recite the subject matter shown in Example 8 of the specification may overcome the rejection, where the claims specifically are amended to recite that that primers of SEQ ID NO: 22 and SEQ ID NO: 23 were used to amplify the E.coli *pgi* gene which encodes phosphoglucose isomerase and that this gene is mutated and inactivated to create host cells deficient in phosphoglucose isomerase activity.

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Conclusion


14. No claim is allowed.

15. Claim 28 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L Fronda whose telephone number is (571)272-0929. The examiner can normally be reached Monday-Friday between 9:00AM - 5:00PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura N Achutamurthy can be reached on (571)272-0928. The fax phone number for the organization where this application or proceeding is assigned is (571)273-8300.

17. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CLF


TEKCHAND SAIDHA
PRIMARY EXAMINER